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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,227	02/27/2002	Alan F. Schatzberg	STAN-261	6936

24353 7590 04/26/2004

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EXAMINER	
JONES, DWAYNE C	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 04/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,227	SCHATZBERG ET AL.	
	Examiner	Art Unit	
	Dwayne C Jones	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,21-23,33 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,21-23,33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/4/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-34 are pending.

2. Claims 1-3, 21-23, 33, and 34 are elected and rejected.

3. Claims 2-20, and 24-32 are nonelected and withdrawn from consideration.

Election/Restrictions

4. Applicant's election with traverse of the election of the antiglucocorticoid of RU486, the therapeutic agent of fluoxetine as the selective serotonin reuptake inhibitor, and the CNS disorder of major depression, in Paper No. filed on November 10, 2003 is acknowledged. The traversal is on the ground(s) that these groups are not separate and distinct. This is not found persuasive because the instant claims are generic to the litany of pharmaceutically active agents that are embraced by the functional descriptions of the terms antiglucocorticoid and therapeutic agent as well as the broad recitation of a CNS disorder.

5. The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

6. The information disclosure statement filed on June 4, 2002 has been reviewed and considered, see enclosed copy of PTO FORM 1449.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over McQuade, R. et al. McQuade, R. et al. teach of therapeutic treatments of mood

disorders with the administration of a variety of pharmaceutically active agents, namely fluoxetine and RU-486, (see abstract). The fact that McQuade, R. et al. are silent to the increasing of the permeability of the blood brain barrier in a patient having a CNS disorder that is amenable to drug therapy and not otherwise indicative of an antiglucocorticoid therapy as well as increasing the therapeutic drug to the CNS would be an inherent property with the administration of the very same glucocorticoid compound of RU 486, the courts have held, *In re Swinehart*, 169 USPQ 226, "a newly discovered property does not necessarily mean that the product is unobvious, since this property may be inherent in the prior art."

In addition, "[i]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . .[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Accordingly, the skilled artisan would have been motivated to present these known pharmaceutical agents, in particular fluoxetine and RU-486, in a combined treatment method because the prior art reference of McQuade, R. et al. specifically teach and provide motivation to the skilled artisan to use these pharmaceuticals to treat the very same ailment, namely mood disorders that would obviously embrace forms of depression.

10. Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over McQuade, R. et al. McQuade, R. et al. teach of therapeutic treatments of mood disorders with the administration of a variety of pharmaceutically active agents, namely

fluoxetine and RU-486, (see abstract). The fact that McQuade, R. et al. are silent to the increasing of the permeability of the blood brain barrier in a patient having a CNS disorder that is amenable to drug therapy and not otherwise indicative of an antiglucocorticoid therapy as well as increasing the therapeutic drug to the CNS would be an inherent property with the administration of the very same glucocorticoid compound of RU 486, the courts have held, *In re Swinehart*, 169 USPQ 226, "a newly discovered property does not necessarily mean that the product is unobvious, since this property may be inherent in the prior art." In addition, [I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . .[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Accordingly, the skilled artisan would have been motivated to present these known pharmaceutical agents, in particular fluoxetine and RU-486, in a combined treatment method because the prior art reference of McQuade, R. et al. specifically teach and provide motivation to the skilled artisan to use these pharmaceuticals to treat the very same ailment, namely mood disorders that would obviously embrace forms of depression.

11. In addition, the printed matter on a label or package insert of a kit or container does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package

insert of a kit and the product, composition, or article of manufacture of a kit or container.

12. See *In re Haller* 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of In re Haller, its is stated that: Whether the statement of intended use appears merely in the claim or in label on the product is immaterial so far as the question of Patentability is concerned. . . In accordance with the patent statutes, an article or composition of matter, in order to patentable, must not only be useful and involve invention, but must also be new. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new.

13. Also see *In re Venezia* 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, *In re Miller* 164 USPQ 46 (CCPA 1969) and *In re Gulak* (CAFC) 217 USPQ 401 relate to a mathematical device and to a measuring cup respectively. In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself, which is a patentable distinction because the function of the device depends upon the printed matter itself, which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles or kits. The

claimed articles of the kit remain fully functional absent the labeling or printed instructions for use.

14. Thus the instructions for use included in a kit or article manufacture constitute an "intended use" for that kit or article of manufacture. Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963).

15. In the instant case, the kit claims are drawn to an old article or composition, which further comprises labeling instructions. The intended use, which is recited on the label or package of the insert, lacks a function relationship because the insert or label does not physically or chemically affect the chemical nature within the article of manufacture, and furthermore, the old article or old composition of the kit can still be used by the skilled artisan for other purposes. Therefore the old article or composition which are comprised with the claimed kit are unpatentable over the prior art, because they function equally effectively with or without the labeling, and accordingly no functional relationship exists between the instructions for use and the composition.

16. Thus the claims are addressed as being drawn to an article of manufacture comprising an old composition of a kit and a package insert, the instructions on the insert bearing no patentable weight with regard to double patenting, 102 and 103 rejections.

Obviousness-type Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1-3, 21, 23, 33, and 34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. U.S. Patent Application Publication No. US 2002/0065259 in view of McQuade, R. et al. First, copending Application No. U.S. Patent Application Publication No. US 2002/0065259 teaches of the administration of glucocorticoid blockers, namely mifepristone, which is also referred to as R486 for the treatment of a disease of CNS as well as increasing the permeability of the blood-brain barrier and enhancing the delivery of a drug to the CNS, (see claims 1-17). Second, McQuade, R. et al. disclose of the administration of fluoxetine for the treatment of mood

disorders, (see abstract). "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . .[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Accordingly, the skilled artisan would have been motivated to present these known pharmaceutical agents, in particular fluoxetine and RU-486, in a combined treatment method because the prior art reference of McQuade, R. et al. specifically teach and provide motivation to the skilled artisan to use these pharmaceuticals to treat the very same ailment, namely mood disorders that would obviously embrace forms of depression.

19. This is a provisional obviousness-type double patenting rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Thursday, and Fridays from 8:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, may be reached at (571) 272-0584. The official fax No. for correspondence is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

DWAYNE JONES
PRIMARY EXAMINER
Tech. Ctr. 1614
April 21, 2004